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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 05/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,982

Applicant(s)

BARRISH ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 7-14 and 16-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 7-14 and 16-19 are currently pending in the application. Claims 7, 8, 10, 12, 14 and 16 were amended in the response filed 6 January 2003 and claim 15 was cancelled.

Election/Restrictions

The subject matter of claims 7-19 other than that wherein:

The compound of formula I as found in claim 7 wherein:

R₁ is hydrogen, or **R₆**

R_{1ab} is hydrogen, **R₆**, or **-OR₆**,

R_{1ac} is hydrogen, **R₆**, or **-OR₆**,

R_{1ad} is hydrogen,

One of **R₂** or **R₃** is hydrogen or **-Z₄-R_{6a}** (wherein **Z₄** is a single bond and **R_{6a}** is alkyl) and the other of **R₂** or **R₃** is **Z₄-R_{6a}** substituted with **Z₃** (wherein **Z₄** is **Z₁₁-C(O)-Z₁₂**, wherein **Z₁₁** and **Z₁₂** are each a single bond, **R_{6a}** is phenyl)

Z₃ is **Z₄-NZ₇Z₈** (wherein **Z₄** is alkyl)

Z₇ and **Z₈** are hydrogen or **Z₄-Z_{6a}** (wherein **Z₄** is a single bond)

Z_{6a} is alkyl

R₆ is alkyl

m is 1

n is 2

Z₁ is hydrogen

Z₂ is hydrogen

X₂ is **NZ_{3a}**

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 Z_{3a} is $C(O)_qZ_{6a}$ q is 1

It is noted that this generic concept is equivalent to the generic concept as found in the final rejection mailed 5 November 2002 but has been rewritten to correspond to the variables as found in applicant's amended claim 7.

The remaining subject matter of claims 7-14 and 16-19 that is not drawn to the above elected invention stands withdrawn under 37 CFR 1.142(b) as being for non elected subject matter, for reasons essentially those given in the last Office actions. The remaining compounds which are not within the generic concept, which are independent and distinct from the generic concept and do not have unity with the species elected and therefore are withdrawn by means of a restriction requirement within the claim are, for example, the compounds wherein:

R1 is -OH, -OR₆, -SH, -SR₆, -C(O)qH, -C(O)qR₆, -O-C(O)qR₆, -SO₃H, -S(O)qR₆, halo, cyano, nitro, -Z₄-NR₇R₈, -Z₄-N(R₉)-Z₅-NR₁₀R₁₁, -Z₄-N(R₁₂)-Z₅-R₆ or -P(O)(OR₆)₂;

R1ab, **R1ac** are -OH, SH, -SR₆, -C(O)qH, -C(O)qR₆, -O-C(O)qR₆, -SO₃H, -S(O)qR₆, halo, cyano, nitro, -Z₄-NR₇R₈, -Z₄-N(R₉)-Z₅-NR₁₀R₁₁, -Z₄-N(R₁₂)-Z₅-R₆ or -P(O)(OR₆)₂;

R1ad is R₆, -OH, -OR₆, -SH, -SR₆, -C(O)qH, -C(O)qR₆, -O-C(O)qR₆, -SO₃H, -S(O)qR₆, halo, cyano, nitro, -Z₄-NR₇R₈, -Z₄-N(R₉)-Z₅-NR₁₀R₁₁, -Z₄-N(R₁₂)-Z₅-R₆ or -P(O)(OR₆)₂;

R2 and **R3** are both H, both equivalent -Z₄-R_{6a}'s, both -Z₄-NR_{7a}R_{8a}, one H and one -Z₄-

NR_{7a}R_{8a}, one Z₄-R_{6a} and one -Z₄-NR_{7a}R_{8a}; **R6** is alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, heterocyclo, or heterocycloalkyl, unsubstituted or substituted with Z₁, Z₂ or one or more groups Z₃; **R6a** is alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl (besides phenyl), aralkyl,

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heterocyclo, or heterocycloalkyl, unsubstituted or substituted with Z1, Z2 or one or more groups Z3; **R6b** are alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, heterocyclo, or heterocycloalkyl, unsubstituted or substituted with Z1, Z2 or one or more groups Z3; **R7a**, **R8a**, **R9**, **R10**, **R11**, **R12** are each independently hydrogen, -Z4R6b, R7a and R8a may together be alkylene, alkenylene, or heteroalkylene, completing a 3-to 8-membered saturated or unsaturated ring with the nitrogen atom to which they are attached, which ring is unsubstituted or substituted with Z1, Z2 and one or more groups Z3, or any two of R9, R10 and R11 may together be alkylene, alkenylene or heteroalkylene completing a 3-to 8-membered saturated or unsaturated ring together with the nitrogen atoms to which they are attached, which ring is unsubstituted or substituted with one or more Z1, Z2 and Z3; **X2** is CZ3a, O or S; **Z3a** is H, hydroxy, optionally substituted alkyl, optionally substituted heterocyclo, optionally substituted aryl, optionally substituted aralkyl, -OZ6, -C(O)qH, -Z4-NZ7Z8 or -Z4-N(Z10)-Z5-Z6; **n** is 1 or 3; **m** is zero or 2; **Z1** and **Z2** are each independently Z6, -OH, -OZ6, -SH, SZ6, -C(O)qH, -C(O)qZ6, -O-C(O)qZ6, -SO3H, -S(O)qZ6, S(O)qN(Z9)Z6, halo, cyano, nitro, -Z4-NZ7Z8, -Z4-N(Z9)-Z5-NZ7Z8, -Z4-N(Z10)-Z5-Z6, -Z4-n(Z10)-Z5-H, oxo, any two of Z1, Z2 and Z3 on a given substituent may together be alkylene or alkenylene completing a 3-to 8-membered saturated or unsaturated ring together with the atoms to which they are attached or any two of Z1, Z2 and z3 on a given substituent may together be -O-(CH2)q-O-; **Z3** is hydrogen, Z6, -OH, -OZ6, -SH, SZ6, -C(O)qH, -O-C(O)qZ6, -SO3H, -S(O)qZ6, S(O)qN(Z9)Z6, halo, cyano, nitro, -Z4-NZ7Z8, -Z4-N(Z9)-Z5-NZ7Z8, -Z4-N(Z10)-Z5-Z6, -Z4-n(Z10)-Z5-H or oxo; Z4 is -Z11-S(O)q-Z12, -Z11-C(S)-Z12-, Z11-O-Z12-, -Z11-S-Z12-, -Z11-O-C(O)-Z12-, Z11-C9O)-O-Z12- or alkyl; **Z5** is a single bond, -Z11-C(O)-Z12-, -

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Z11-S(O)q-Z12, -Z11-C(S)-Z12-, Z11-O-Z12-, -Z11-S-Z12-, -Z11-O-C(O)-Z12-, Z11-C9O)-O-Z12- or alkyl; **Z6** is (i)alkyl, hydroxyalkyl, alkoxyalkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, alkylaryl, cycloalkylaryl, heterocyclo, or heterocycloalkyl, (ii) a group (i) which is itself substituted by one or more of the same or different groups (i), (iii) a group (i) or (ii) which is independently substituted by one or more of the groups (2) to (15) of the definition of Z1; **Z6a** is (i) hydroxyalkyl, alkoxyalkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, cycloalkenylalkyl, aryl, aralkyl, alkylaryl, cycloalkylaryl, heterocyclo, or heterocycloalkyl, (ii) a group (i) which is itself substituted by one or more of the same or different groups (i), (iii) a group (i) or (ii) which is independently substituted by one or more of the groups (2) to (15) of the definition of Z1; **Z7** and **Z8** may together be alkylene, alkenylene, or heteroalkylene completing a 3-to 8-membered saturated or unsaturated ring together with the atoms to which they are attached, which ring is unsubstituted or substituted with one or more Z1, Z2 and Z3 or Z7 or Z8 together with Z9 may be alkylene, alkenylene, or heteroalkylene completing a 3-to 8-membered saturated or unsaturated ring together with the nitrogen atoms to which they are attached, which ring is unsubstituted or substituted with one or more Z1, Z2 and Z3; **Z9** and **Z10** are each independently hydrogen or -Z4-Z6a-; **Z11** and **Z12** are each independently a single bond, alkylene, alkenylene or alkynylene. Some specific species of the withdrawn compounds are the species of example 11 (page 51), which contains the substituent pyridine, the species of example 58 (page 84), which contains the substituent piperidine and the species of example 435 (page 124), which contains the substituent morpholine, etc.

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The above mentioned withdrawn compounds which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups which differ from those of the elected invention such as cyano, OH, halo, nitro, pyridine, piperidine, morpholine, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 568 subclasses 700(+) (hydroxy), class 544, subclasses 106(+) (morpholine), class 546 subclasses 184(+) (piperidine), class 546 subclasses 1(+) (pyridine), class 558 subclasses 303(+) (cyano), class 570 subclass 101(+) (halo), class 564 subclass 1(+) (amino nitrogen containing), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

Therefore, Applicants' traversal of the restriction requirement has been considered but is not found persuasive. Applicants argue that the examiners recasting of the claims to the generic concept improperly limits the scope of Applicants claims. However, the generic concept does

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not improperly limit the scope of Applicants claims. Applicants' claims involve more than one independent or distinct invention. Under 35 U.S.C. 121, the claims may be restricted and the examination limited to a restricted invention. Accordingly, restriction as has been presented in this application is proper. The requirement to restrict is repeated and made final.

Objections

Claims 7-14 and 16-19 are objected to as containing non-elected subject matter. Claims 7-14 and 16-19 presented drawn solely to the elected invention as identified supra would appear allowable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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Joseph McKane
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